Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed November 30, 2009. Currently, claims 1-69 remain pending of which claims 11-64 were previously withdrawn. Claims 1-10 and 65-69 have been rejected and claim 68 has been objected to. Favorable consideration of the following remarks is respectfully requested.

Claim objections

Claim 68 has been objected to because of a formality noted by the Examiner. The claim has been amended as suggested and Applicants respectfully request that the objection be withdrawn.

Claim Rejections – 35 USC § 112

Claim 67 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants believe that claim 67 as currently amended is sufficiently clear to satisfy 35 U.S.C. §112 second paragraph.

The current language is believed to properly encompass the various medical devices and their respective configurations to which the limitation may apply. While some such medical devices, especially as deployed, may be described as having a proximal end and a distal end, the device itself prior to insertion may not properly admit of those designations. Other devices, for example certain stents, may be configured such that the first and second ends of the device are essentially indistinguishable. To properly describe the relationship between the overall medical device and the first composite elongated member and/or the second composite elongated member it is expedient to define a central longitudinal axis having arbitrarily assigned associated directions which are opposed and then to refer the orientation(s) of remaining components, i.e., the first and second composite elongated members, to those directions relative to the medical device. Accordingly, the central longitudinal axis may be said to have a first direction along the longitudinal axis and an opposed second direction along the longitudinal axis.

While Applicants might have chosen to specify left/right or North/South as descriptors for the relative directions, those designations would not properly apply to a medical device no longer in the intended, but otherwise unspecified orientation. Accordingly, Applicants believe that the claim is sufficiently clear and provides a pair of directions relative to the medical device to which the components, and their respective axes, may be referred. In claim 67, that takes the form of specifying that the axis of the first composite elongated member and the axis of the composite medical device are displaced from each other at that end of the first composite elongated member which extends in the direction designated the first direction relative to the composite medical device. If upon reflection, the Examiner continues to feel that clarity is an issue, she is invited to offer alternative language which would be acceptable.

> Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. (MPEP 2173.02)

Claim 66 does not include "axis". Was some other claim intended? The Examiner is invited to clarify the comment.

Claim Rejections – 35 USC § 102

Claims 1-4, 10, and 65-69 were rejected under 35 U.S.C. 102(b) as anticipated by Tomonto (U.S. Patent No. 6,425,855). After careful review, Applicant must respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, *814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (See MPEP § 2131).* Nowhere does Tomonto appear to teach or suggest, "a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first

material, the outer member surrounding and encasing the inner member, wherein the second material is more elastic than the first material", as recited in claim 1.

Instead, Tomonto appears to teach a stent (composite medical device), the struts of which (composite elongated members) comprise a two layer lamellar composite depicted in Fig. 3. Accordingly, the inner superelastic material layer (80) appears to be inner with respect to the medical device as a whole, but only forms a second adjacent outer layer with respect to the composite elongate member. Additionally, the outer layer of the medical device (stent) does not appear to surround and encase the superelastic material, but merely lies parallel to it as a component of the composite elongated member. The entire inner, with respect to the stent, surface of the superelastic layer of the strut appears to be exposed and thus the superelastic layer is not surrounded by the outer, with respect to the stent, layer. As seen in Fig. 3 and as described in the cited passage, stainless steel layer (100) is adjacent to, but does not surround Nitinol layer (110) in the composite elongated members (struts) of the stent.

The Examiner's attention is particularly directed to the plain language of claim 1 in which the outer member of the first composite elongated member surrounds and encompasses the inner member of the first composite elongated member. It is that composite elongated member which forms a component of the composite medical device and thus it is within the composite elongated member that the outer member must surround and encase the inner member. The relationship between the inner and outer members of the composite elongated member and the overall composite medical device is not specified by claim 1; however one of ordinary skill in the art would readily appreciate that in the exemplary composite medical device (10) of Fig. 1, it is outer material (26) of the composite elongated member (18) of claim 1 which forms the "inner" material of the filter (composite medical device) by virtue of being present on both the inner and outer surface of the filter as it surrounds and encases the inner member of the composite elongated member (18).

Although the Examiner has asserted that Fig. 1 of Tomonto shows the outer layer is external to and directly attached to the inner layer on multiple sides, Applicants respectfully disagree. As seen in Fig. 3, identified as "a partial cross sectional view of the stent shown in FIG. 2 taken along line 3–3", layer 110 is not surrounded on multiple

sides by layer 100 as it forms an adjacent, parallel component of the two-layered loop (70) which most nearly appears to correspond to the composite elongated member of the claim. As discussed above the "inner" location of the layer (110) relative to the stent as a whole appears entirely irrelevant to the claimed relationship between the inner and outer members within each component composite elongated member.

Although the Examiner has asserted that the superelastic material is "more elastic" than the plastically deformable material as stainless steel or titanium, this does not appear to be supported by the disclosure of Tomonto. No such comparison appears to be presented in the cited passage. The mere fact that stainless steel or titanium have associated therewith a plastic yield strain says nothing about the degree to which elastic recovery (elasticity) is present. Indeed, when the stainless steel or titanium plastically deform, it is because they behave inelastically. At col. 2, lines 48-51, Tomonto appears to describe permanent (plastic) deformation of Nitinol as well thereby indicating that each of the components of the stents of Tomonto may plastically deform regardless of their relative elasticity. Further, the property of superelasticity is not equivalent to elasticity, but rather indicates an elastic (reversible) response to an applied stress, caused by a phase transformation between the austenitic and martensitic phases of a crystal. Elasticity, superelasticity and a plastic yield (permanent deformation) are not generally directly comparable without further information regarding the materials and the thermal and mechanical conditions to which the samples have been subjected.

Further the Examiner has characterized Tomonto as "teaching the outer plastically deformable layer as sandwiching the inner superelastic material". To the extent that this teaching is present, Tomonto apparently only teaches an A-B-A sandwich structure resulting from cutting slots into a tube having a wall comprising three concentric layers thereby leaving the core exposed along the edges of the cuts which does not overlap either "surrounding" (that which extends on <u>all</u> sides of simultaneously; encircle) or "encasing" (enclose in, or as if in, a case) [enclose: to shut in <u>all</u> around; hem in; fence in (Webster's New World College Dictionary, 4th Ed.)] for the simple reason that the jelly of the "sandwich" appears to be fully exposed on at least two sides of the layer.

Accordingly, Tomonto does not appear to anticipate *each and every element as set forth in the claim* and to do so in as great detail as presented in the claim and

Applicants respectfully request that the rejection of claim 1 be withdrawn.

With regard to the dependent claims, the Examiner asserts: "Since the inner layer of the stent comprises Nitinol, the inner layer biases the medical device to the expanded position", citing the background at col. 1, lines 43-60. Applicants respectfully disagree with both the interpretation of the cited text and the Examiner's unsupported conclusion. The mere fact that Nitinol has material properties suited to allowing fabrication of a self-expanding article does not teach that articles fabricated from Nitinol are inherently self-expanding. The properties of Nitinol stents depend upon the thermomechanical history of the stent. For example, Nitinol stents may be self-collapsing or simply neutral with respect to self-expansion or contraction in a state in which they respond elastically to applied stress/strain. At col. 3, lines 10-34, Tomonto appears to disparage the prior art self-expanding stents to which the cited passage refers and then continues to suggest the superiority of an articulated stent in which the articulated regions are relatively elastic.

Although the Examiner has asserted that claims 6-8 are product-by-process claims. It is well established that the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.) In that ruling, the court indicated that grinding (mechanical removal) is capable of construction as structural limitation when compared to etching (chemical removal). (MPEP 2113)

Accordingly claims 2-4, 10, and 65-69, which depend from independent claim 1 and include significant additional limitations, are believed to be not anticipated by Tomonto and Applicants respectfully request that the rejections be withdrawn.

Claim Rejections – 35 USC § 103

Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonto in view of Moore (U.S. Published Patent Application No. 2004/0024444). After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed above, Tomonto appears to disclose a stent having an inner layer of a first material and an outer layer of a second material, however Tomonto does not appear to disclose a composite medical device comprising ""a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first material, the outer member surrounding and encasing the inner member, wherein the second material is more elastic than the first material". Additionally, nowhere does the polymeric coating of Moore appear to remedy the deficiencies of Tomonto as applied to claim 1.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claim5, which depends from nonobvious independent claim 1, also is believed to be nonobvious and Applicants respectfully request that the rejection be withdrawn.

In the Response to Arguments, the Examiner yet again fails to differentiate the structure of a hollow stent having a two-layered tubular wall from the two-layered composite elongated struts which comprise the stent. This leads to contradictions in the application of descriptive terms. The stent appears to have an axial lumen (to be hollow) and thus does not appear to have a solid cross-section as required of a composite elongated member. See col. 3, lines 57-59: "Each of the graft member has a first end, a second end, a wall section disposed therebetween and a lumen extending therethrough." The only portions of the stent of Tomonto which appear to have both innermost and outermost layers are the grafts (20, 30, and 40) having the partial cross-section illustrated

in Fig. 3. In those regions, outer layer 100 never appears to be present on the innermost surface of the stent, within the lumen, and thus never surrounds and encases the innermost layer. As illustrated three of the four surfaces of the innermost layer 110 are free of the material of outer layer 100. Accordingly, the stent of Tomonto does not supply the structure of a composite elongated member as recited in claim 1.

Turning now to the composite strut regions of the grafts, which appear more nearly to correspond to composite elongated members, the struts of the grafts appear to be explicitly described and illustrated (Fig. 3) as two-layer lamellar structures comprising generally parallel wall section layers. As seen in Fig. 3 which presents a cross-section of a graft in the region of a strut, the layer 100 never appears to surround the layer 110 and thus the strut of Tomonto does not supply the structure of a composite elongated member as recited in claim 1.

This leaves only the articulation regions (80, 90) between the grafts which are described as "made from a superelastic material" (col. 5, lines 41-42) and thus are not composite and do not appear to be ""a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first material", as recited in claim 1, much less to provide a structure in which an outer layer surrounds and encases an inner layer.

Accordingly, no portion of the stent of Tomonto or the struts of Tomonto or the articulation regions of Tomonto appear to have the requisite structure to support a §102 rejection.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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